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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,393	10/10/1997	DENISA D. WAGNER	CFBF-P02-002	6939

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	08/948,393	WAGNER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-73,77-81 and 83-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-73, 77-81, 83-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 11/17/03, has been entered.

According to the Listing of the Claims, claims 71 and 90 are currently amended.
However, currently amended claims 71 and 90 are not marked to show the changes made in the current amendment relative to the immediate prior version.
See 1272 Off. Gaz. Pat. Office 197 (July 29, 2003), 68 Fed. Reg. 38611 (June 20, 2003) (final rule).

In the interest of compact prosecution, this Office Action will address the claims as currently written, rather than sending out a Nonresponsive Communication.

However, applicant is required to provide claims consistent with Revised Amendment Practice 37 CFR 1.121.

Claims 71 and 90 have been amended.
Claims 91-95 have been added.

Claims 1-70, 74-76, 82 have been canceled previously.

Claims 71-73, 77-81 and 83-95 are pending.

Claims 71-73, 77-81 and 83-95 are under consideration as they read on the elected invention, drawn to methods of treating or inhibiting atherosclerosis with PSGL-1, fragments and chimeric constructs thereof.

Claims 71-73, 77-81 and 83-90 as they read on methods of treating or inhibiting atherosclerosis with agents other than PSGL-1 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 11/17/03.
The rejections of record can be found in the previous Office Actions.

3. Claims 71-73, 77-81 and 83-90 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Cummings et al. (U.S. Patent No. 5,464,778) (see entire document) for the reasons set forth in the previous Office Actions and addressed herein.

Claims 71-73, 77-81 and 83-90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. patent No. 5,464,778) in view of Larsen et al. (U.S. Patent No. 5,840,679) for the reasons set forth in the previous Office Actions and addressed herein.

Applicant's arguments in conjunction with the declaration under 37 C.F.R. § 1.131, filed 3/18/03, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

However, the following is noted.

In contrast to applicant's assertions that the examiner has conceded to a number of points, including the broad discovery encompassing the specific treatment method described in the pending claims, the following of record is reiterated for applicant's convenience as to what the previous Office Action did address.

Applicant asserts that the original claims encompassed the genus as well as the species and it is only as a result of the restriction requirement imposed by the examiner that applicant was required to limit their claims to selected species. Applicant believes that the possession of the genus is sufficient to constitute possession of the species. Applicant believe that the 131 Declaration is adequate and sufficient to antedate the Cummings et al. reference since the declaration shows that applicant was in possession of the genus which include the species of Cummings et al.

In contrast to applicant's assertions, applicant was not in complete possession of the entire genus of "agents for inhibiting an interaction between P-selectin and a ligand of P-selectin and between E-selectin and a ligand of E-selectin" for treating for treating or inhibiting atherosclerosis".

In contrast to applicant's assertions, the priority date of administering the claimed PSGL-1 to treat atherosclerosis is the filing date of priority application USSN 08/253,663, filed 6/3/94.

Applicant has not provided sufficient objective evidence that the limited disclosure set forth in the declaration under 37 C.F.R. § 1.131, filed 3/18/03, renders obvious the admininstration of PSGL-1 to treat atherosclerosis prior to applicant's priority date of 6/3/94.

Further, it is noted that the evidence set forth in the declaration under 37 C.F.R. § 1.131, filed 3/18/03, is less that the claimed invention, including the use of PSGL-1 to treat atherosclerosis.

Again, there is insufficient evidence set forth in the declaration under 37 C.F.R. § 1.131, filed 3/18/03, for administering "agents for inhibiting an interaction between P-selectin and a ligand of P-selectin and between E-selectin and a ligand of E-selectin" for treating for treating or inhibiting atherosclerosis", much less the claimed inhibitor PSGL-1. Applicant has not provided evidence of prior completion of one or more species which put him or her in possession of the asserted claimed genus or the claimed PSGL-1 species prior to the reference.

It is noted that an applicant of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the result obtained from species than those specifically enumerated. See Enzo Biochem v. Gen-Probe, Inc. 323 F.3d 956, 964 (Fed. Cir. 2002).

Here, again it is noted that evidence set forth in the declaration under 37 C.F.R. § 1.131, filed 3/18/03, does not provide sufficient objective evidence of administering an agent for treating atherosclerosis, much less PSGL-1. Given the relative incomplete understanding in the biotechnological field involved, namely treating atherosclerosis, and the lack of a reasonable correlation between the limited disclosure in the declaration under 37 C.F.R. § 1.131, filed 3/18/03, and the broad scope of protection asserted by applicant, applicant has not provided evidence of prior completion of one or more species which put him or her in possession of the asserted claimed genus or the claimed PSGL-1 species prior to the reference.

The following of record is reiterated for applicant's convenience.

Applicant has asserted that the Declaration by the co-inventors demonstrates that the conception of the instant invention occurred as early as 1988 and that an actual reduction to practice occurred as early as 9/13/93. The time period between 11/16/92 and 9/13/93 was consumed by the development of a knockout mouse model for atherosclerosis and the testing of the mouse model to verify the inventive concept. It was noted that the conclusion of the results of the experiment were collected and analyzed on or about 5/6/94.

Applicant's has relied upon the statement: " Macrophages eat bits of activated platelets. ELAM-1 = Padgem. Do monocytes bind to Padgem on platelets. Padgem is an opsonizing agent to get rid of debris of platelets." Applicant asserted their conception of a functional relationship between E-selectin and P-selectin, and that P-selectin mediates the binding of platelets to macrophages (leukocytes implicated in atherosclerosis).

Applicant relied upon the preparing a P-selectin knock-out mouse to study the role of P-selectin in atherosclerosis by feeding the P-selectin deficient mice with a lipid diet. The results of this study demonstrated a reduction in the size of atherosclerotic lesions in P-selectin deficient mice.

Applicant asserted that based upon these results that inhibitors of P-selectin/ligand binding and/or E-selectin/ligand binding would be useful for the treatment or inhibition of atherosclerosis, constituting an actual reduction to practice the claimed invention.

The evidence, submitted is insufficient to establish a reduction to practice of the invention in this country prior to the effective date of the prior art.

The 37 CFR 1.131 declaration must establish possession of either the whole invention claimed or something falling within the claim in the sense that the claims as a whole reads on it. In re Tanczyn 146 USPQ 298 (CCPA 1965). See MPEP 715.02.

Applicant has not overcome the prior art rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the references(s) or the activity.

The test is whether the facts set out in the affidavit are such as would persuade one skilled in the art that the application possessed so much of the invention as is shown in the references. In re Schaub 190 USPQ 324 (CCPA 1976). See MPEP 715.03.

Applicant's evidence of conception and diligence does not address the critical elements of the instant claims which are drawn to a method of treating or inhibiting atherosclerosis in a mammal by administering PSGL-1.

There is insufficient evidence the ordinary artisan would have taken applicant statement: " Macrophages eat bits of activated platelets. ELAM-1 = Padgem. Do monocytes bind to Padgem on platelets. Padgem is an opsonizing agent to get rid of debris of platelets." to establish possession of treating atherosclerosis in a mammal by administering PSGL-1.

Similarly there is insufficient evidence the ordinary artisan would have taken applicant preparation of a P-selectin knock-out mouse to study the role of P-selectin in atherosclerosis by feeding the P-selectin deficient mice with a lipid diet to establish possession of treating atherosclerosis in a mammal by administering PSGL-1.

Further, it was noted that applicant's evidence relies upon experimental animals serves as model systems to selectively investigate different steps of the injury cascade providing specific insights into key mechanisms operating in diseases. While applicant's studies with a P-selectin knockout mouse may have provided insights into the role of P-selectin to atherosclerosis, there is insufficient evidence and correlation of establishing possession of treating atherosclerosis in a mammal by administering PSGL-1, particularly given the absence of any disclosure of administering PSGL-1 in applicant's 131 Declaration and Exhibits.

Also, applicant has not provided objective evidence that applicant was in possession of PSGL-1 itself as well as its use as a therapeutic agent in treating atherosclerosis prior to the disclosure of the prior art. Applicant's reliance on a generic concept of a possible role of P-selectin in atherosclerosis and subsequent findings in an experimental animal model does not support the use of PSGL-1 in treating atherosclerosis.

Absent a clear support or facts are establishing applicant's assertions of conception and diligence (and reduction to practice or subsequent reduction to practice) before the prior art, applicant's arguments are not found persuasive and the rejection is maintained for the reasons of record (e.g., see Paper Nos. 44, 46 and 48).

Again it is noted that Cummings et al. teach the use of PSGL in the treatment of leukocyte adherence, inflammation and coagulation, including ischemia-reperfusion injury and atherosclerosis (see column 18, paragraphs 5-8; columns 19-20, overlapping paragraph).

Therefore, applicant's arguments are not found persuasive for the reasons of record.

5. Claims 71-73, 77-81 and 83-95 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 40-41, 45, 49-52, 56, 59-60, 73-74 (or appropriate pending claims) as they read on the use of PSGL-1 to treat atherosclerosis of copending application Serial No. 09/436,076 and

claims 39-88 (or appropriate pending claims)as they read on the use of PSGL-1 to treat atherosclerosis of copending application USSN 09/883,642 for the reasons of record set forth in the previous Office Actions.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating atherosclerosis with the same or nearly the same PSGL-1, fragments and chimeric constructs thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment, filed 11/17/03, reiterates the previous indication that applicant is prepared to file a terminal disclaimer in this application to overcome this rejection provided that the application is otherwise considered to be in proper condition for allowance.

6. No claim is allowed

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 5, 2004